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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,618	09/25/2003	Stephen T. Flock	D6476	6784

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EXAMINER

HUH, BENJAMIN

ART UNIT PAPER NUMBER

3767

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/670,618

Applicant(s)

FLOCK ET AL.

Examiner

Benjamin Huh

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8,13-19,21-26,28,29,31,32,34-37,43,44,50,51,61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,8,13-19,21-26,28,29,31,32,34-37,43,44,50,51,61 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-6, 8, 13-19, 21-26, 28-29, 31-32, 34-37, 43-44, 50-51, & 61-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended claim 1 states on line 9 "means to collect a tissue or biochemical sample during ablation ...", there is no evidence or support in the specification that states that the means to collect a tissue or biochemical tissue occur during ablation and therefore is new matter. Amended claim 1 also states on line 12 "... wherein said pharmaceutical is in a separate container ...", there is no evidence or support in the specification that states that there is a separate container for the pharmaceutical operably connected to the device when it is seen that "separate" means separate with respect to another container. The specification does not disclose one container for the abrasive material and a second container for the pharmaceutical. With respect to the rest of the claims, they are rejected for being dependent upon a rejected independent claim.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling how a pressurized gas functions as a means to drive an abrasive member at high frequencies. How one is able to attain high frequency driving forces using these methods and/or materials is not enabled in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4-6, 8, 13-19, 21-26, 28-29, 31-32, 34-37, 43-44, 50-51, & 61-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The number of containers involved can be deemed to be indefinite as well as the definition of the term "separate" found in line 12 of claim 1. Amended claim 1 line 12 states " ... wherein said pharmaceutical is in a separate container ...", the term "separate" can be deemed in two ways in which the container can be physically separated distance-wise from the device while operably connected by a tube or other means or it can mean a separate container such as another container meaning that the claim must contain more than one container. Either way, both terms are not disclosed in the specification and are deemed to be new matter. In claim 1, lines 3-6 give the possibility for 0-1 containers wherein if the abrasive material is delivered onto a tissue

via a container then there is one container, if the abrasive material is already attached to the abrasive member then currently there is 0 containers claimed. With respect to lines 9-10, a means to collect the tissue could be either a container or an absorptive medium according to the specification page 18 line 19 – page 19 line 4 and page 25 lines 5-16. Therefore this portion of the claims can also have 0-1 containers. Therefore, if the term separate means another defined container then the claim requires there to be 2-3 container while if the term separate is defined as being physically separated distance-wise from the device then there can be 1-3 containers in the claim. Appropriate action is required.

Specification

The amendment filed 3/9/06 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the original disclosure on page 25 lines 5-16 does not disclose separate containers for a pharmaceutical and the ablated tissue, the disclosure states that container can be modified to hold ablated tissue or other biomolecule and the abrasive, or alternatively to have the container hold the pharmaceutical, it does not disclose there to be more than one container. It also does not state that there can be separate container for the abrasive material and the ablated tissue it only states that they can be used to contain both.

Other new matter includes the collection of biomolecules may take place through absorption by an absorptive material 70 in contact with the treated skin or directly into a container 75, no where in the disclosure does it state that the absorptive material can be in contact with the treated skin, it just states in the specification pages 18 line 19 – page 19 line 4 & page 25 lines 5-16 that the collection means can be a container or an absorptive medium.

Applicant is required to cancel the new matter in the reply to this Office Action.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they disclose new matter in the new replacement drawing sheets received on 3/9/06. The newly amended drawing disclose a container 75 and a absorptive medium 70 together in the drawing, there is no support in the specification for there to be both a container for ablated tissue or other biomolecule AND an absorptive medium. The drawings also disclose a separate container 76 for holding the abrasive material which is not supported in the specification. The drawings also disclose containers 75 & 76 to have a height higher than that of element 12 or element 42 or having a height below element 55 and so on as well as the fact that the specification does not disclose the location of the two containers or that of the absorptive medium with respect to the two containers.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, every possibility of 1-3

containers must be shown or the feature(s) canceled from the claim(s) as disclosed above in the 112 "indefinite" rejection, such as the container for the ablated tissue, the container for the pharmaceutical, and the possible container for the abrasive material depending on the definition of "separate" also discussed above. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

With respect to the claims, examiner would like to note that Claim 1 does NOT invoke 35 USC 112 6th paragraph on means plus function since the claims do not explicitly state "...means ... for ..." OR "... step ... for...".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 5, 6, 8, 14, 18, 19, 21-26, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over SUROFF (US Patent No. 5,150,492) in view of EARL (US Pub. No. 2004/0020508a1). Suroff discloses a device for altering tissue comprising an abrasive member contacting abrasive material on tissue or thereon and means to drive the member at high frequency and a means to collect a tissue. The device is capable of use with various tissues and various lubricant (i.e., water) and pharmaceuticals. Now even though Suroff does not explicitly disclose a separate container attention is directed to Earl. The Earl reference discloses a separate container 19 for containing a desired substance such as a pharmaceutical for delivery, see figures 5-7. Therefore, it would be obvious to one of ordinary skill in the art at the time of the

invention to modify the device of Suroff with the container as taught by Earl in order to provide a convenient container for quick access to the desired substance and efficiency.

Claims 1, 2, 4-6, 8, 13-18, 20-26, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over BERNAZ (WO 02/053046) (See US Pub. No. 2004/0092959 for English version) in view of TAPPER (US Patent No. 6235013B1). Bernaz discloses a device for altering or ablating tissue comprising an abrasive member contacting abrasive material on tissue or thereon, electro or magneto responsive material (motor) means to drive the abrasive member at high frequency, abrasive material of aluminum oxide 50-90 microns, lubricant comprising water, electrophoretic driving means, and a container formed by ridges capable of holding pharmaceuticals until delivery by mechanical pressure. See 2004/0092959 paragraphs 0019, 0025, 0031, 0032, 0046-0047, 0052, 0055, 0062, and 0063. The device is capable of use with various tissues and pharmaceuticals. Now even though Bernaz does not explicitly disclose the use of a separate container for the pharmaceutical attention is directed to Tapper. The Tapper reference teaches the use of a separate pharmaceutical container elements 18a & 18b in figures 2-3. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Bernaz with the teachings of Tapper in order to provide a convenient container for quick access to the desired substance and efficiency.

Claims 1, 2, 4-6, 8, 13-26, 28, 31, 34-37, 43, 44, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over WEAVER (US Pub. No. 2002/0065533 A1) in view of TAPPER (US Patent No. 6235013B1). Weaver discloses a device for ablating tissue using an abrasive member (microparticle) that can be driven at high frequencies

to contact abrasive material (microparticles) delivered onto a tissue via a container (0042-0045). The pressurized gas driving forces disclosed by Weaver are capable of driving microparticles at high frequencies by using intermittent driving forces. Weaver discloses means to deliver a pharmaceutical to the tissue (0113-0117) that inherently includes a container and can be applied using electrophoresis. The microparticles include ice and aluminum oxide with sizes within 30-120 microns (0034, 0055-0063). The gas carrier serves as a lubricant with the microparticles so they flow easily; also blood and other body fluids (i.e., lipids) provide an electrically conductive lubricant. Weaver discloses collecting biomolecules for sampling (01 14), and electrodes, conductive fluid interface, and controller capable of monitoring electrical property of the tissue (001 7, 0018). Re claim 37, the device disclosed by Weaver is capable of performing the claimed function of monitoring. Weaver discloses a radiant energy source, light detector and controller capable of monitoring a change in optical property of the tissue. Now even though Weaver does not explicitly disclose the use of a separate container for the pharmaceutical attention is directed to Tapper. The Tapper reference teaches the use of a separate pharmaceutical container elements 18a & 18b in figures 2-3. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Weaver with the teachings of Tapper in order to provide a convenient container for quick access to the desired substance and efficiency.

Claims 1, 2, 4-6, 8, 13, 14, 17, and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over HICKOK et al. (US Pub. No. 2003/0096213) in view of TAPPER (US Patent No. 6235013B1). Hickok discloses a device for ablating tissue

using diamond abrasive on the ablating device and a supply of pharmaceuticals to be delivered to the ablation site. Now even though Hickok does not explicitly disclose the use of a separate container for the pharmaceutical attention is directed to Tapper. The Tapper reference teaches the use of a separate pharmaceutical container elements 18a & 18b in figures 2-3. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Hickok with the teachings of Tapper in order to provide a convenient container for quick access to the desired substance and efficiency.

Claims 34, 35, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over BERNAZ in view of TAPPER as applied to claims 26 and 1 above, and further in view of EGGERS (US Patent No. 6,066,134). Bernaz in view of Tapper discloses the claimed invention except for monitoring feedback using an electrical property of the tissue with the device. Eggers teaches monitoring feedback using a heartbeat to perform a safe ablation procedure. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Eggers in the device of Bernaz to increase the safety of the ablation procedure for better patient outcome.

Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over WEAVER in view of TAPPER as applied to claim 1 above, and further in view of EGGERS (US Patent No. 6,159,194). Weaver in view of Tapper discloses the claimed invention including monitoring temperature, but is silent on the structure relied upon to

monitor the temperature (0117). Eggers teaches monitoring a thermal property of the tissue using infrared sensors. The use of an infrared detector and controller analyze the data from an energy source and detector is inherent in the disclosed device because it measures temperature. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Eggers in the device of Weaver in order to maintain safe operating temperatures during the ablation procedure.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over BERNAZ, WEAVER, or HICKOK in view of TAPPER as applied to claim 20 above, and further in view of UNGER (US Patent No. 6,416,740). Bernaz, Weaver, or Hickok in view of Tapper discloses the claimed invention except for a reservoir with a permeable membrane to release a pharmaceutical to the tissue. Unger teaches the use of a permeable membrane to release the pharmaceutical in a patch applied to the skin of a patient (see 69:1 1-14). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Unger in the device of Bernaz, Weaver, or Hickok in order to provide a convenient drug delivery system through the skin to achieve therapeutic results.

Claims 19, 61, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over BERNAZ, WEAVER, or HICKOK in view of TAPPER as applied to claim 1 above, and further in view of MELBOUCI et al. (US Patent No. 6,562,090). Bernaz, Weaver, or Hickok in view of Tapper discloses the claimed invention except for using a lubricant of water and glycerol with the abrasive. Melbouci teaches using water

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and glycerol as a lubricant to provide a stabilized suspension of abrasive in lubricant (see claim 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Melbouci in the device of Bernaz, Weaver, or Hickok in order to facilitate the flow of the abrasive.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over WEAVER in view of TAPPER as applied to claim 31 above, and further in view of FUISZ (US Patent No. 3,918,433). Weaver in view of Tapper discloses the claimed invention except for using cotton with the collection container. Fuisz teaches using cotton in a collection container to provide sorption capacity in excess of the container volume. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Fuisz in the device of Weaver to provide for a collection container to hold fluid.

Response to Arguments

Applicant's arguments filed 3/9/06 have been fully considered but they are not persuasive.

Applicant's arguments with respect to the 35 USC 112 enablement rejection are not persuasive with respect to the pressurized gas. Even though Weaver gives an example of the use of a pressurized gas this is only one method of use for pressurized gas. Pressurized gas can be utilized in many different ways as a drive means and the

applicant does not disclose in which fashion the gas is utilized to drive the abrasive member at high frequencies. Therefore, it is still deemed to not be enabled.

Applicant argues that Suroff does not disclose a device effective to ablate tissue. The examiner disagrees because the device disclosed by Suroff is fully capable of ablating tissue, the use of soft bristles is not required and the device does run at a high frequency, see col. 6 line 64 – col. 7 line 2. Applicant's claims are directed to a device and not a method, and therefore any functional limitations must be capable of being performed by the prior art, not explicitly stated as being performed as in method steps.

Applicant argues that Suroff does not disclose a means of collecting a tissue or biological sample, which is operably connected to the device or a means to deliver a pharmaceutical to tissue. Examiner disagrees because Suroff does disclose a means of collecting a tissue which is deemed to be the area between and underneath the bristles which would be fully capable of collecting ablated tissue or biomolecule also the cavities shown in Suroff in the area of the bristles are capable of containing pharmaceuticals and has structure that is capable of applying a mechanical pressure to delivery the pharmaceuticals.

Applicant argues that Bernaz does not disclose means to deliver a pharmaceutical to tissue or means to collect a tissue or biomolecule. The examiner disagrees and refers to cavities & ridges seen in figures 4 & 5b that are capable of containing pharmaceuticals and structure that is capable of applying mechanical pressure to deliver the pharmaceuticals as well as cavities to collect a tissue or

biomolecule sample. Applicant does not positively claim a pharmaceutical, but rather, structure that would be capable of delivering a pharmaceutical.

Applicant argues that the references do not disclose the treating product to be contained in a separate container. Examiner would like to note that the separate container is deemed to be new matter as discussed above in the 112 rejections. No where in the specification does it state that there is or can be a separate container for the pharmaceutical. With respect to the separate container, it would be obvious to one of ordinary skill in the art to modify the device to utilize a separate container to contain the pharmaceuticals, see the rejection above.

Applicant argues that Weaver does not teach a device having an abrasive material. Examiner disagrees and refers to the microparticles that are deemed to be disposed on the tissue surface and are fully capable of ablating tissue.

Applicant argues that Hickok does not teach a means to collect a tissue or biochemical sample. Examiner disagrees and refers to the cavities seen in the disclosed devices that are capable of collecting tissue or a sample. Note applicant's claims do NOT invoke 112 6th and therefore are not utilizing means-plus function language.

Applicant argues that Eggers in view of Bernaz does not teach elements of the instant application such as monitoring feedback. Examiner disagrees and refers to the electrical properties of Eggers with respect to the electrodes and other components which are fully capable of monitoring feedback using an electrical property of the tissue.

Applicant argues that Unger does not teach a device for ablating tissue. Examiner states that Unger does not have to teach a device for ablating tissue because

Unger is applied to the references in further view of references Bernaz, Weaver, and Hickok. Applicant also argues that it would not be obvious to combine the devices of Bernaz or Weaver or Hickok in view of Unger. Examiner disagrees. The Unger reference discloses a permeable membrane to release a pharmaceutical to the tissue in a patch and would be obvious to modify utilize these teaching the references of Bernaz, Hickok, or Weaver in order to provide a convenient drug delivery system through the skin to achieve therapeutic results.

Applicant argues that the Melbouci reference is non-obvious over Bernaz, Weaver, or Hickok since they supposedly do not teach all the elements of claim 1. Examiner disagrees and states that it would be obvious to modify the references with the teachings of Melbouci in order to utilize lubricant of water and glycerol with the abrasive in order to facilitate the flow.

Applicant argues that the Fuisz reference does not teach or suggest the sampling device with the tissue ablating system. Examiner disagrees since Fuisz teaches the use of cotton with a collection container in order to provide sorption capacity and would therefore be obvious to modify the device of Weaver with the teachings of Fuisz in order to provide sorption capacity.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN SIRMONS
PRIMARY EXAMINER

A handwritten signature in cursive script that reads "Kevin C. Sirmons". The signature is written in black ink and is positioned below the printed name and title of the examiner.